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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/750,280	12/29/2000	D. Scott Wilbur	33700WC005	6495

441 7590 09/09/2003

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WASHINGTON, DC 20036

EXAMINER

WELLS, LAUREN Q

ART UNIT	PAPER NUMBER
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1617

DATE MAILED: 09/09/2003

23

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/750,280

Applicant(s)

WILBUR ET AL.

Examiner

Lauren Q Wells

Art Unit

1617

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 30 July 2003.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 33-97 is/are pending in the application.
- 4a) Of the above claim(s) 42-54, 60, 61, 63, 68, 69, 71, 72, 75-87 and 90-97 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 33-41, 55-59, 62, 64-67, 70, 73, 74, 88 and 89 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☒ None of:
1. ☒ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ | 6) <input type="checkbox"/> Other: |

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DETAILED ACTION

Claims 33-97 are pending. Claims 42-54, 60-61, 63, 68-69, 71-72, 75-87 and 90-97 are withdrawn from consideration, as they are directed to non-elected subject matter. The Amendment filed 7/30/03, Paper No. 22, amended claims 33, 37, 55, 56, 64, 65, 88 and 89.

A certified copy of the priority document is still missing. While it appears that the priority document was filed 4/18/01, the priority document is not in the case. Thus, it is respectfully requested that a new priority document be provided.

Response to Applicant's Arguments/Amendment

The Applicant's arguments filed 7/30/03 (Paper No. 22) to the rejection of claims 33-41, 54-59, 62, 64-67, 70-74 and 88-89 made by the Examiner under 35 USC 102, 103, and 101 have been fully considered and deemed not persuasive.

Applicant's arguments and amendment filed 7/30/03 (Paper No. 22) are sufficient-in-part to overcome the 35 USC 112 rejections in the previous Office Action. See below for details.

Double Patenting Rejection Maintained

The rejection of claims 33-41, 55-59, 62, 64-67 and 70 under 35 U.S.C. 101 as claiming the same invention as that of claims 1-10, 17-19, 21-23 of copending Application No. 09/519998 is MAINTAINED for the reasons set forth in the Office Action mailed 2/12/03, Paper No. 19, and those found below.

Applicant request, "this matter be deferred until an indication of allowable subject matter". However, this rejection is maintained.

112 Rejection Maintained

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The rejection of claims 70 and 88-89 under 35 U.S.C. 112 is MAINTAINED for the reasons set forth in the Office Action mailed 2/12/03, Paper No. 19, and those found below.

-Regarding claim 70, Applicant states "Claim 70 has been amended to remove the formality as to the missing period in the claim by adding the phrase "wherein such member is stabilized against enzymatic cleavage in linker1"". This argument is not persuasive, as claim 70 has not been amended.

-Regarding claims 88 and 89, Applicant states "Claims 88 and 89 have been amended to remove the terms "optionally modified" and "having a desired biological property retained". This argument is not persuasive, as these claims are still vague and indefinite. Does the biomolecule refer to the "bimolecular reactive moiety" or to the "biomolecule" that is conjugated to the reagent?

102 Rejection Maintained

The rejection of claims 33-35, 39-41, 55-59, 62, 64-67, 73-74 and 88-89 under 35 U.S.C. 102(b) as being unpatentable over Wilbur is MAINTAINED for the reasons set forth in the Office Action mailed 2/12/03, Paper No. 19, and those found below.

Applicant argues, "Claim 33 as set forth herein, applicants respectfully submit that the Wilbur patent does not show a first linker stabilized to inhibit enzymatic cleavage of the affinity ligand". This argument is not persuasive. The Examiner respectfully points out that the first linker taught by Wilbur is the same first linker taught by the instant invention (trioxadamine). Thus, the first linker taught by Wilbur and the first linker of the instant invention have the same properties, as a compound and its properties are inseparable.

103 Rejection Maintained

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The rejection of claims 33-41, 55-59, 62, 64-67, 70, 73-74 and 88-89 under 35 U.S.C. 103(a) as being unpatentable over Wilbur et al. in view of Griffiths (5,482,698) is MAINTAINED for the reasons set forth in the Office Action mailed 2/12/03, Paper No. 19, and those found below.

Applicant argues, "The Griffiths document fails to provide any motivation for a person skilled in the art to arrive at the present invention. A person skilled in the art would not be lead to combine Wilbur and Griffiths with a view of solving the problems as discussed in the present invention and achieve a successful solution to that problem". This argument is not persuasive. First, the Examiner respectfully points out that this argument is not commensurate in scope with the instant claims which do not recite steps to solving a problem or achieving a successful solution to a problem. Additionally, Applicant has provided not data that the instant invention is unexpected over that of the prior art. Furthermore, the Examiner respectfully points out that Griffiths is merely relied upon to show that homobiotin and biotin are interchangeable and obvious variants.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 33-41, 54-59, 62, 64-67, 70-74 and 88-89 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

(i) The phrase "derivation of avidin" and "derivation of streptavidin" in claim 33 (lines 10 and 12) is vague and indefinite, as the metes and bounds of this claim are unascertainable.

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What is derivation of avidin or streptavidin? Does it mean the addition of an amino group? A hydroxyl group? A nitro group? The specification does not define these phrases and one of ordinary skill in the art would not be apprised of their meaning.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Lauren Q Wells whose telephone number is (703) 305-1878. The examiner can normally be reached on M-F (7-4:30), with alternate Mondays off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreeni Padmanabhan can be reached on (703)305-1877. The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306.


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Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-1234.

lqw


SREENI PADMANABHAN
PRIMARY EXAMINER 9/8/03